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Form PTO 1449 US Department of Commerce Patent and Trademark Office	ATTY DOCKET NO: P-PM 3474	SERIAL NO.: 09/288,344
	APPLICANT: Seidman and Théorêt	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE: 4/8/99	GROUP: Art Unit 1623

U.S. PATENT DOCUMENTS

EXAM. INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
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**	AR	Aarbakke et al., "Thiopurine biology and pharmacology," Second Thiopurine Symposium, 19-20 (1996).
Me	AS!	Andersen et al., "Pharmacokinetics, dose adjustments, and 6-mercaptopurine/methotrexate drug interactions in two patients with thiopurine methyltransferase deficiency," <u>Acta Paediatr.</u> , 87:108-111 (1998).
Me	AT	Balis et al., "Pharmacokinetics and Pharmacodynamics of Oral Methotrexate and Mercaptopurine in Children With Lower Risk Acute Lymphoblastic Leukemia: A Joint Children's Cancer Group and Pediatric Oncology Branch Study," <u>Blood</u> , 92(10):3569-3577 (1998). (11/15/98)
Me	AU!	Bergan et al., "Patterns of Azathioprine Metabolites in Neutrophils, Lymphocytes, Reticulocytes, and Erythrocytes: Relevance to Toxicity and Monitoring in Recipients of Renal Allografts," <u>Ther. Drug Monit.</u> , 19:502-509 (1997).

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** See PTO-892 for complete citation.

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<i>Me</i>	AV!	Bergan et al., "Monitored High-Dose Azathioprine Treatment Reduces Acute Rejection Episodes After Renal Transplantation," <u>Transplantation</u> , 66(3):334-339 (1998). (08/15/98)
<i>Me</i>	AW	Black et al., "Thiopurine Methyltransferase Genotype Predicts Therapy-Limiting Severe Toxicity from Azathioprine," <u>Annals of Internal Medicine</u> , 129(9):716-718 (1998). (11/01/98).
<i>Me</i>	AX!	Bökkerink et al., "6-Mercaptopurine: Cytotoxicity and Biochemical Pharmacology in Human Malignant T-Lymphoblasts," <u>Biochem. Pharm.</u> , 45(7):1455-1463 (1996).
<i>Me</i>	AY!	Bostrom and Erdmann, "Cellular Pharmacology of 6-Mercaptopurine in Acute Lymphoblastic Leukemia," <u>The American Journal of Pediatric Hematology/Oncology</u> , 15(1):80-86 (1993).
<i>Me</i>	AZ!	Cattan et al., "6-Mercaptopurine pharmacokinetics and blood lymphocyte subpopulations in patients with Crohn's disease treated with azathioprine," <u>Gastroenterol. Clin. Biol.</u> , 22:160-167 (1998).
<i>Me</i>	BR!	Chan et al., "Azathioprine Metabolism: Pharmacokinetics of 6-Mercaptopurine, 6-Thiouric Acid and 6-Thioguanine Nucleotides in Renal Transplant Patients," <u>J. Clin. Pharmacol.</u> , 30:358-363 (1990).
<i>Me</i>	BS!	Chrzanowska and Krzymanski, "Determination of 6-Thioguanine and 6-Methylmercaptopurine Metabolites in Renal Transplantation Recipients and Patients With Glomerulonephritis Treated With Azathioprine," <u>Ther. Drug Monit.</u> , 21:231-237 (1999).
<i>Me</i>	BT	Colonna and Korelitz, "The Role of Leukopenia in the 6-Mercaptopurine-Induced Remission of Refractory Crohn's Disease," <u>Amer. J. Of Gastroenterology</u> , 89:362-366 (1994). (March, 1994).

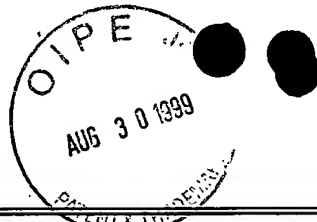
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<i>Me</i>	BU	Coulthard et al., "The Relationship Between Thiopurine Methyltransferase Activity and Genotype in Blasts From Patients With Acute Leukemia," <u>Blood</u> , 92(8):2856-2862 (1998). (10/15/98).
<i>Me</i>	BV!	Cuffari et al., "6-Mercaptopurine metabolism in Crohn's disease: correlation with efficacy and toxicity," <u>Gut</u> , 39:401-406 (1996).
<i>Me</i>	BW!	Cuffari et al., "Quantitation of 6-thioguanine in peripheral blood leukocyte DNA in Crohn's disease patients on maintenance 6-mercaptopurine therapy," <u>Can. J. Physiol. Pharmacol.</u> , 74:580-585 (1996).
<i>Me</i>	BX!	Dervieux and Boulieu, "A HPLC Method for the Monitoring of Human Red Cell 6-Thioguanine and Methyl 6-Mercaptopurine in a Single Run," <u>Purine and Pyrimidine Metabolism in Man IX</u> , 140:729-734 (1998). (Plenum Press, NY)
<i>Me</i>	BY!	Dervieux and Boulieu, "Simultaneous determination of 6-thioguanine and methyl 6-mercaptopurine nucleotides of azathioprine in red blood cells by HPLC," <u>Clin. Chem.</u> , 44(3):551-555 (1998).
<i>Me</i>	BZ	Dubinsky et al., "6-MP Metabolite Levels Predict Clinical Efficacy and Drug Toxicity in Pediatric IBD," <u>J. Pediatr. Gastro. Nutr.</u> , 27:465 (1998). (October, 1998).
<i>Me</i>	CR!	El-Gamel et al., "Effect of Allopurinol on the Metabolism of Azathioprine in Heart Transplant Patients," <u>Transplantation Proceedings</u> , 30:1127-1129 (1998).
<i>Me</i>	CS!	Erb et al., "Pharmacokinetics and metabolism of thiopurines in children with acute lymphoblastic leukemia receiving 6-thioguanine versus 6-mercaptopurine," <u>Cancer Chemother. Pharmacol.</u> , 42:266-272 (1998).

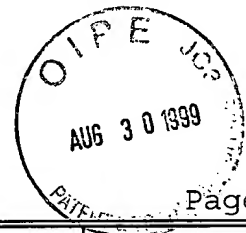
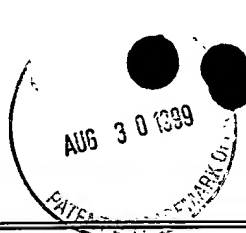
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Me	CU ¹	Giverhaug et al., "Increased Concentrations of Methylated 6-Mercaptopurine Metabolites and 6-Thioguanine Nucleotides in Human Leukemic Cells In Vitro by Methotrexate," <u>Biochem. Pharmacol.</u> , 55:1641-1646 (1998). (Issue No. 10).
Me	CV ¹	Jacqz-Aigrain et al., "Thiopurine methyltransferase activity in a French population: h.p.l.c. assay conditions and effects of drugs and inhibitors," <u>Br. J. Clin. Pharmacol.</u> , 38:1-8 (1994).
Me	CW ¹	Keuzenkamp-Jansen et al., "Thiopurine methyltransferase: a review and a clinical pilot study," <u>J. Chromatogr. B</u> , 678:15-22 (1996).
Me	CX ¹	Kirschner, "Safety of Azathioprine and 6-Mercaptopurine in Pediatric Patients With Inflammatory Bowel Disease," <u>Gastroenterology</u> , 115:813-821 (1998). (Issue No. 4)
Me	CY ¹	Klemetsdal et al., "Identification of factors regulating thiopurine methyltransferase activity in a Norwegian population," <u>Eur. J. Clin. Pharmacol.</u> , 44:147-152 (1993).
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Me	DS!	Lennard and Maddocks, "Assay of 6-thioguanine nucleotide, a major metabolite of azathioprine, 6-mercaptopurine and 6-thioguanine, in human red blood cells," <u>J. Pharm. Pharmacol.</u> , 35:15-18 (1982).
Me	DT	Lennard et al., "Childhood Leukaemia: A Relationship Between Intracellular 6-Mercaptopurine Metabolites and Neutropenia," <u>Br. J. Clin. Pharmacol.</u> , 16:359-363 (1983).
Me	DU!	Lennard et al., "Thiopurine pharmacogenetics in leukemia: Correlation of erythrocyte thiopurine methyltransferase activity and 6-thioguanine nucleotide concentrations," <u>Clin. Pharm. Ther.</u> , 41(1):18-25 (1987).
Me	DV	Lennard et al., "Genetic variation in response to 6-mercaptopurine for childhood acute lymphoblastic leukaemia," <u>Lancet</u> , 336:225-229 (1990) (7/28/90)
Me	DW!	Lennard L., "The clinical pharmacology of 6-mercaptopurine," <u>Eur. J. Clin. Pharmacol.</u> , 43:329-339 (1992).
Me	DX!	Lennard and Singleton, "High-performance liquid chromatographic assay of the methyl and nucleotide metabolites of 6-mercaptopurine: quantitation of red blood cell 6-thioguanine nucleotide, 6-thioinosinic acid and 6-methylmercaptopurine metabolites in a single sample," <u>J. Chromatog.</u> , 583:83-90 (1992).
Me	DY!	Lennard et al., "Is 6-thioguanine more appropriate than 6-mercaptopurine for children with acute lymphoblastic leukaemia?" <u>Br. J. Cancer</u> , 68:186-190 (1993).
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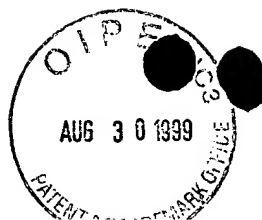
Me	ER ¹	Lennard et al., "Intracellular metabolites of mercaptopurine in children with lymphoblastic leukaemia: a possible indicator of non-compliance?" <u>Br. J. Cancer</u> , 72(4):1004-1006 (1995).
Me	ES ¹	Lennard et al., "Thiopurine drugs in the treatment of childhood leukaemia: the influence of inherited thiopurine methyltransferase activity on drug metabolism and cytotoxicity," <u>Br. J. Clin. Pharmacol.</u> , 44:455-461 (1997).
Me	ET ¹	Lennard L., "Clinical Implications of Thiopurine Methyltransferase-Optimization of Drug Dosage and Potential Drug Interactions," <u>Ther. Drug Monit.</u> , 20:527-531 (1998). (Issue No. 5).
Me	EU ¹	Lilleyman and Lennard, "Mercaptopurine metabolism and risk of relapse in childhood lymphoblastic leukaemia," <u>Lancet</u> , 343:1188-1190 (1994). (5/14/94)
Me	EV	McLeod et al., "Thiopurine methyltransferase activity in American white subjects and black subjects," <u>Clin. Pharmacol. Ther.</u> , 55:15-20 (1994). (1/94).
Me	EW	McLeod et al., "Polymorphic Thiopurine Methyltransferase in Erythrocytes Is Indicative of Activity in Leukemic Blasts From Children With Acute Lymphoblastic Leukemia," <u>Blood</u> , 85(7):1897-1902 (1995). (04/10/95).
Me	EX	Pearson et al., "Azathioprine and 6-Mercaptopurine in Crohn Disease, A Meta-Analysis," <u>Ann. Intern. Med.</u> , 123(2):132-142 (1995). (7/15/95).
Me	EY	Present et al., "6-Mercaptopurine in the Management of Inflammatory Bowel Disease: Short- and Long-Term Toxicity," <u>Annals of Internal Medicine</u> , 111:641-649 (1989). (10/15/89).
Me	EZ	Relling et al., "Prognostic Importance of 6-Mercaptopurine Dose Intensity in Acute Lymphoblastic Leukemia," <u>Blood</u> , 93(9):2817-2823 (1999). (05/01/99).

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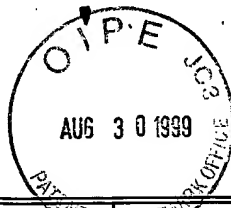
<i>Me</i>	FR	Sandborn and Tremaine, "Measurement of Thiopurine Methyltransferase (TMPT) Activity In Patients With Inflammatory Bowel Disease (IBD) Does Not Predict Side Effects From Treatment With 6-Mercaptopurine (6-MP) Or Azathioprine," <u>Gastroenterology</u> , 104(4):A774 (1993). (April, 1993).	
<i>Me</i>	FS	Sandborn et al., "An Intravenous Loading Dose of Azathioprine Decreases the Time to Response in Patients With Crohn's Disease," <u>Gastroenterology</u> , 109:1808-1817 (1995). (December, 1995).	
<i>Me</i>	FT	Sandborn, "A Review of Immune Modifier Therapy for Inflammatory Bowel Disease: Azathioprine, 6-Mercaptopurine, Cyclosporine, and Methotrexate," <u>Amer. J. Of Gastroenterology</u> , 91(3):423-433 (1996). (March, 1996).	1996.
<i>Me</i>	FU	Sandborn, "6-MP Metabolite Levels: A Potential Guide to Crohn's Disease Therapy," <u>Gastroenterology</u> , 113(2):690-692 (1997).	
<i>Me</i>	FV [!]	Schütz et al., "Should 6-Thioguanine Nucleotides Be Monitored in Heart Transplant Recipients Given Azathioprine?" <u>Ther. Drug Monit.</u> , 18:228-233 (1996) (Issue No. 3).	
<i>Me</i>	FW [!]	Schmiegelow and Bruunshuus, "6-Thioguanine nucleotide accumulation in red blood cells during maintenance chemotherapy for childhood acute lymphoblastic leukemia, and its relation to leukopenia," <u>Cancer Chemother. Pharmacol.</u> , 26:288-292 (1990).	
<i>Me</i>	FX	Schmiegelow et al., "Risk of Relapse in Childhood Acute Lymphoblastic Leukemia Is Related to RBC Methotrexate and Mercaptopurine Metabolites During Maintenance Chemotherapy," <u>J. Clin. Oncol.</u> , 13(2):345-351 (1995). (02/95).	(02/95).
<i>Me</i>	FY	Snow et al., "The Role of Genetic Variation in Thiopurine Methyltransferase Activity and the Efficacy and/or Side Effects of Azathioprine Therapy in Dermatologic Patients," <u>Arch. Dermatol.</u> , 131:193-197 (1995). (February, 1995).	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

<i>Me</i>	FZ ¹	Vogt et al., "The importance of methylthio-IMP for methylmercaptopurine ribonucleoside (Me-MPR) cytotoxicity in Molt F4 human malignant T-lymphoblasts," <u>Biochimica et Biophysica Acta</u> , 1181:189-194 (1993).
<i>Me</i>	GR	Warren et al., "Quantitation of 6-Thioguanine Residues in Peripheral Blood Leukocyte DNA Obtained from Patients Receiving 6-Mercaptopurine-based Maintenance Therapy," <u>Cancer Res.</u> , 55:1670-1674 (1995). (04/14/95).
<i>Me</i>	GS ¹	Welch et al., "Pharmacokinetics of Mercaptopurine: Plasma Drug and Red Cell Metabolite Concentrations After an Oral Dose," <u>Ther. Drug Monit.</u> , 19:382-385 (1997).
<i>Me</i>	GT ¹	Zins et al., "Simultaneous Determination of Azathioprine and Its Metabolites in Plasma Using a High Pressure Liquid Chromatography Assay," <u>Gastroenterology</u> , 110(4):A1054 (1996).
<i>Me</i>	GU ¹	Zins et al., "A Dose Ranging Study of Azathioprine Pharmacokinetics Following Single Dose Administration of a Delayed Release Oral Azathioprine Formulation," <u>Gastroenterology</u> , 110(4):A1054 (1996).
<i>Me</i>	GV ¹	Zins et al., "A Dose-Ranging Study of Azathioprine Pharmacokinetics After Single-Dose Administration of a Delayed-Release Oral Formulation," <u>J. Clin. Pharmacol.</u> , 37:38-46 (1997).

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GW ¹	Candy et al., "A controlled double blind study of azathioprine in the management of Crohn's disease," <u>Gut</u> , 37:674-678 (1995).
GX ¹	Connell et al., "Bone marrow toxicity caused by azathioprine in inflammatory bowel disease," <u>Gut</u> , 34:1081-1085 (1993).
GY ¹	Goldstein et al., "Toxicities and infections associated with chronic 6-mercaptopurine (6-MP) use in Crohn's disease (CD): Do we need to discontinue treatment?" <u>Gastroenterology</u> , 114:A4041 (1998). Abst. A4041.
GZ	Hawthorne et al., "Randomized controlled trial of azathioprine withdrawal in ulcerative colitis," <u>Br. Med. J.</u> , 305:20-22 (1992). (07/04/92).

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<i>Jke</i>	HR	Lennard and Lilleyman, "Variable 6-mercaptopurine metabolism and treatment outcome in childhood lymphoblastic leukemia," <u>J. Clin. Oncol.</u> , 7:1816-1823 (1989). (December, 1989).
<i>Jke</i>	HS	Lennard et al., "Pharmacogenetics of acute azathioprine toxicity: relationship to thiopurine methyltransferase genetic polymorphism," <u>Clin. Pharmacol. Ther.</u> , 46:149-154 (1989). (August, 1989).
<i>Jke</i>	HT	Markowitz et al., "Long-term 6-mercaptopurine treatment in adolescents with Crohn's disease," <u>Gastroenterol.</u> , 99:1347-1351 (1990). (November, 1990).
<i>Jke</i>	HU	Markowitz et al., "Immunosuppressive therapy in pediatric inflammatory bowel disease: results of a survey of the North American Society for Pediatric Gastroenterology and Nutrition. Subcommittee on immunosuppressive use of the Pediatric IBD Collaborative Research Forum, <u>Am. J. Gastroenterol.</u> , 88:44-48 (1993). (January, 1993).
<i>Jke</i>	HV !	Markowitz et al., "6-mercaptopurine (6-MP) & prednisone therapy for newly diagnosed pediatric Crohn's disease (CD): A prospective multicenter, placebo-controlled clinical trial," <u>Gastroenterol.</u> , 114:A4227 (1998).
<i>Jke</i>	HW !	Markowitz et al., "Relationship of leukopenia to 6-MP induced remission of Crohn's disease," <u>J. Pediatr. Gastroenterol. Nutr.</u> , 27:A8 (1998).
<i>Jke</i>	HX	Present et al., "Treatment of Crohn's disease with 6-mercaptopurine: a long-term, randomized, double-blind study," <u>N. Engl. J. Med.</u> , 302:981-987 (1980). (May 1, 1980).
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<i>He</i>	HZ ¹ —	Van Os et al., "Azathioprine pharmacokinetics after intravenous, oral, delayed release oral and rectal foam administration," <u>Gut</u> , 39:63-68 (1996).
<i>He</i>	IR ¹ —	Van Os et al., "Simultaneous determination of azathioprine and 6-mercaptopurine by high-performance liquid chromatography," <u>J. Chromatog. B</u> , 679:147-154 (1996).
<i>He</i>	IS —	Willoughby et al., "Controlled trial of azathioprine in Crohn's disease," <u>Lancet</u> , 731:944-947 (1971). (October 30, 1971).

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